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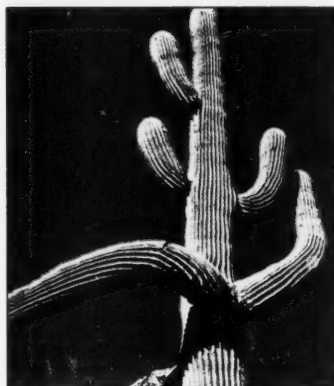
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Minipress® B.I.D. Dosage Convenience (prazosin HCl) Capsules 1mg 2mg 5mg

BRIEF SUMMARY

MINIPRESS® (prazosin hydrochloride) CAPSULES For Oral Use

INDICATIONS: MINIPRESS® (prazosin hydrochloride) is indicated in the treatment of hypertension. As an antihypertensive drug, it is mild to moderate in activity. It can be used as the initial agent or it may be employed in a general treatment program in conjunction with a diuretic and/or other antihypertensive drugs as needed for proper patient response.

WARNINGS: MINIPRESS (prazosin hydrochloride) may cause syncope with sudden loss of consciousness. In most cases this is believed to be due to an excessive postural hypotensive effect, although occasionally the syncope episode has been preceded by a bout of severe tachycardia with heart rates of 120-160 beats per minute. Syncope episodes have usually occurred within 30 to 90 minutes of the initial dose of the drug; occasionally they have been reported in association with rapid dosage increases or the introduction of another antihypertensive drug into the regimen of a patient taking high doses of MINIPRESS (prazosin hydrochloride). The incidence of syncope episodes is approximately 1% in patients given an initial dose of 2 mg or greater. Clinical trials conducted during the investigational phase of this drug suggest that syncope episodes can be minimized by limiting the initial dose of the drug to 1 mg, by subsequently increasing the dosage slowly, and by introducing any additional antihypertensive drugs into the patient's regimen with caution (see **DOSAGE AND ADMINISTRATION**). Hypotension may develop in patients given MINIPRESS who are also receiving a beta-blocker such as propranolol.

If syncope occurs, the patient should be placed in the recumbent position and treated supportively as necessary. This adverse effect is self-limiting and in most cases does not recur after the initial period of therapy or during subsequent dose titration.

Patients should always be started on the 1 mg capsules of MINIPRESS (prazosin hydrochloride). The 2 and 5 mg capsules are not indicated for initial therapy.

More common than loss of consciousness are the symptoms often associated with lowering of the blood pressure, namely, dizziness and lightheadedness. The patient should be cautioned about these possible adverse effects and advised what measures to take should they develop. The patient should also be cautioned to avoid situations where injury could result should syncope occur during the initiation of MINIPRESS (prazosin hydrochloride) therapy.

Usage in Pregnancy: Although no teratogenic effects were seen in animal testing, the safety of MINIPRESS (prazosin hydrochloride) in pregnancy has not been established. MINIPRESS (prazosin hydrochloride) is not recommended in pregnant women unless the potential benefit outweighs potential risk to mother and fetus.

Usage in Children: No clinical experience is available with the use of MINIPRESS (prazosin hydrochloride) in children.

ADVERSE REACTIONS: The most common reactions associated with MINIPRESS (prazosin hydrochloride) therapy are: dizziness 10.3%, headache 7.8%, drowsiness 7.6%, lack of energy 6.9%, weakness 6.5%, palpitations 5.3%, and nausea 4.9%. In most instances side effects have disappeared with continued therapy or have been tolerated with no decrease in dose of drug.

The following reactions have been associated with MINIPRESS (prazosin hydrochloride), some of them rarely (in some instances exact causal relationships have not been established):

Gastrointestinal: vomiting, diarrhea, constipation, abdominal discomfort and/or pain.

Cardiovascular: edema, dyspnea, syncope, tachycardia.

Central Nervous System: nervousness, vertigo, depression, paresthesia.

Dermatologic: rash, pruritus, alopecia, lichen planus.

Genitourinary: urinary frequency, incontinence, impotence, priapism.

EENT: blurred vision, reddened sclera, epistaxis, tinnitus, dry mouth, nasal congestion.

Other: diaphoresis.

Single reports of pigmentary mottling and serous retinopathy and a few reports of cataract development or disappearance have been reported. In these instances, the exact causal relationship has not been established because the baseline observations were frequently inadequate.

In more specific slit-lamp and fundoscopic studies, which included adequate baseline examinations, no drug-related abnormal ophthalmological findings have been reported.

DOSAGE AND ADMINISTRATION: The dose of MINIPRESS (prazosin hydrochloride) should be adjusted according to the patient's individual blood pressure response. The following is a guide to its administration:

Initial Dose: 1 mg two or three times a day (See Warnings.)

Maintenance Dose: Dosage may be slowly increased to a total daily dose of 20 mg given in divided doses. The therapeutic dosages most commonly employed have ranged from 6 mg to 15 mg daily given in divided doses. Doses higher than 20 mg usually do not increase efficacy; however, a few patients may benefit from further increases up to a daily dose of 40 mg given in divided doses. After initial titration some patients can be maintained adequately on a twice daily dosage regimen.

Use With Other Drugs: When adding a diuretic or other antihypertensive agent, the dose of MINIPRESS (prazosin hydrochloride) should be reduced to 1 mg or 2 mg three times a day and re-titration then carried out.

HOW SUPPLIED: MINIPRESS (prazosin hydrochloride) is available in 1 mg (white #431), 2 mg (pink and white #437) capsules in bottles of 250, 1000, and unit dose institutional packages of 100 (10 x 10's); and 5 mg (blue and white #438) capsules in bottles of 250, 500 and unit dose institutional packages of 100 (10 x 10's).

More detailed information available on request.

References: 1. O'Connor DJ, Preston RA, Sasso EH: Renal perfusion changes during treatment of essential hypertension: Prazosin versus propranolol. *J Cardiovasc Pharmacol* 1(suppl):S38-S42, 1979. 2. Falase AO, Salako LA: The effect of prazosin combined with a diuretic, polythiazide, in hypertensive Africans. *Curr Ther Res* 25:10-15, 1979. 3. Okun R, Maxwell M: Long-term antihypertensive therapy with prazosin plus a diuretic. *J Cardiovasc Pharmacol* 1(suppl):S21-S27, 1979. 4. Kirkendall WM, Hammond JJ, Thomas JC, et al: Prazosin and clonidine for moderately severe hypertension. *JAMA* 240 (23): 2553-2556, December 1, 1978. 5. Harter HR, Delmez JA: Effects of prazosin in the control of blood pressure in hypertensive dialysis patients. *J Cardiovasc Pharmacol* 1(suppl):S43-S55, 1979. 6. Leren P, Fosb PD, Helgeland A, et al: Effect of propranolol and prazosin on blood lipids: The Oslo study. *Lancet* 4-6, July 5, 1980. 7. Lowenstein J, Neusy A-J: The biochemical effects of antihypertensive agents and the impact on atherosclerosis. *J Cardiovasc Pharmacol* 4 (suppl 2):S262-S264, 1982. 8. Kokubu T, Itoh I, Kurita H, et al: Effect of prazosin on serum lipids. *J Cardiovasc Pharmacol* 4 (suppl 2):S228-S232, 1982. 9. Velasco M, Silva H, Morillo J, et al: Effect of prazosin on blood lipids and on thyroid function in hypertensive patients. *J Cardiovasc Pharmacol* 4 (suppl 2):S225-S227, 1982.

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BRIEF SUMMARY

Slo-bid™

100 mg, 200 mg
and 300 mg Gyrocaps®

(theophylline, anhydrous)

Timed Release Capsules

INDICATIONS: For relief and/or prevention of symptoms from asthma and reversible bronchospasm associated with chronic bronchitis and emphysema.

CONTRAINDICATIONS: Slo-bid™ is contraindicated in individuals who have shown hypersensitivity to any of its components or to xanthine derivatives.

WARNINGS: Status asthmaticus is a medical emergency. Optimal therapy frequently requires additional medication including corticosteroids when the patient is not rapidly responsive to bronchodilators.

Since excessive theophylline doses may be associated with toxicity, periodic measurement of serum theophylline levels is recommended to assure maximal benefit without excessive risk. Incidence of toxicity increases at serum levels greater than 20 µg/ml. Although early signs of theophylline toxicity, such as nausea and restlessness, are often seen, in some cases ventricular arrhythmias or seizures may be the first signs of toxicity.

Many patients who have excessive theophylline serum levels exhibit tachycardia. Theophylline preparations may worsen pre-existing arrhythmias.

USAGE IN PREGNANCY: Safe use in pregnancy has not been established relative to possible adverse effects on fetal development, but neither have adverse effects on fetal development been established. This is, unfortunately, true for most antiasthmatic medications. Therefore, use of theophylline in pregnant women should be balanced against the risk of uncontrolled asthma.

PRECAUTIONS: Mean half-life in smokers is shorter than non-smokers. Therefore, smokers may require larger doses of theophylline. Theophylline should not be administered concurrently with other xanthine preparations. Use with caution in patients with severe cardiac disease, severe hypoxemia, hypertension, hyperthyroidism, acute myocardial injury, cor pulmonale, congestive heart failure, liver disease, and in the elderly (especially males) and in neonates. Great caution should be used in giving theophylline to patients with congestive heart failure. Such patients have shown markedly prolonged theophylline blood levels with theophylline persisting in serum for long periods following discontinuation of the drug. Use theophylline cautiously in patients with a history of peptic ulcer. Theophylline may occasionally act as a local gastrointestinal irritant, although G.I. symptoms are more commonly centrally mediated and associated with high serum concentration.

ADVERSE REACTIONS: The most consistent adverse reactions are due usually to overdose, and are:

Gastrointestinal: nausea, vomiting, epigastric pain, hematemesis, diarrhea.

Central nervous system: headaches, irritability, restlessness, insomnia, reflex hyperexcitability, muscle twitching, clonic and tonic generalized convulsions.

Cardiovascular: palpitation, tachycardia, extrasystoles, flushing, hypotension, circulatory failure, ventricular arrhythmias.

Respiratory: tachypnea.

Renal: albuminuria, increased excretion of renal tubular cells and red blood cells, potentiation of diuresis.

Others: hyperglycemia and inappropriate ADH syndrome.

DRUG INTERACTIONS:

Drug	Effect
Aminophylline with Lithium	Increased excretion of Lithium
Carbonate	Carbonate
Aminophylline with Propranolol	Antagonism of Propranolol effect
Theophylline with Furosemide	Increased Diuresis
Theophylline with Hexamethonium	Decreased Hexamethonium-induced Chronotropic effect
Theophylline with Reserpine	Tachycardia
Theophylline with clindamycin, lincomycin, troleandomycin, or erythromycin	Increased theophylline blood levels
Theophylline with Chlordiazepoxide	Chlordiazepoxide-induced fatty acid metabolism

HOW SUPPLIED: Slo-bid™ Gyrocaps® 100 mg are available in bottles of 100 (NDC 0067-0100-68), Slo-bid™ Gyrocaps® 200 mg are available in bottles of 100 (NDC 0067-0200-68) and Slo-bid™ Gyrocaps® 300 mg are available in bottles of 100 (NDC 0067-0300-68).

CAUTION: Federal law prohibits dispensing without prescription. Consult complete product information before prescribing.



WILLIAM H. RORER, INC.
Fort Washington, Pennsylvania U.S.A. 19034

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